

JUN 21 2001

K010838

Sponsor:  
JOMED

Fox PTA Catheter  
Traditional 510(k) Premarket Notification

### 510(k) SUMMARY – Fox PTA Catheter

**Submitter Name:** Jomed AG

**Submitter Address:** Amphauptstrasse, Postfach  
CH-8222 Beringen, Switzerland

**Contact Person:** Rudi Ott

**Phone Number:** + 41 52 674 8505

**Fax Number:** +41 52 674 8540

**Date Prepared:** 20 March 2001

**Device Trade Name:** Fox PTA Catheter

**Device Common Name:** Peripheral Transluminal Angioplasty Catheter

**Classification Name:** 21 CFR 870.1250 Percutaneous Catheter

**Predicate Devices:**

- Guidant VIATRAC PTA Catheter, K000101
- NuMED Ghost II PTA Catheter, K003972

**Device Description:** The JOSTENT® Fox PTA Catheter consists of a double lumen catheter with a balloon located at the distal tip. The catheter will be available in diameters of 3.0, 4.0, 5.0, 6.0, 7.0, 8.0 mm and a length of 40 mm. The catheter has a usable length of 75 cm and is compatible with 0.035" diameter guidewires.

**Intended Use:** The Fox PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistulae.

**Device Technological Characteristics and Comparison to** The Fox PTA Catheter is made of similar materials, is available in similar diameters and lengths, has a similar design, and the same indications for use as the predicate

**Predicate Device(s):** devices and other currently marketed PTA Catheters.

**Performance Data:** Bench and biocompatibility testing in accordance with the recommendations from relevant FDA guidance demonstrates the safety and effectiveness of the Fox PTA Catheter.

**Conclusion:** The Fox PTA Catheter is substantially equivalent to the claimed predicate devices and other currently marketed PTA Catheters.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 21 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Eminent Research Systems  
c/o Mr. Glenn N. Byrd  
Director, Regulatory Affairs  
1700 Rockville Pike  
Rockville, MD 20852

Re: K010838  
Trade Name: FOX PTA Catheter 3.0, 4.0, 5.0, 6.0, 7.0, and 8.0 x  
Regulation Number: 870.1250  
Regulation Class: II (two)  
Product Code: DQY and LIT  
Dated: June 5, 2001  
Received: June 5, 2001

Dear Mr. Byrd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

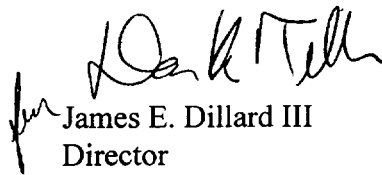
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 Mr. Glenn N. Byrd

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the printed name.

James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Sponsor:  
JOMED

Fox PTA Catheter  
Traditional 510(k) Premarket Notification

510(k) Number (if known):

K010838

Device Name:

Fox PTA Catheter

**Indications for Use:**

The Fox PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistulae.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K010838

Prescription  
Use

X

OR

Over-The-Counter  
Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)